REMARKS

In the Office Action mailed September 7, 2007 from the United States Patent and Trademark Office, claims 1-9 and 23-26 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

Applicants respectfully provide the following:

Claims 27-39 are new.

M.P.E.P. § 2164.04 sets forth that "[Before] any analysis of enablement can occur, it is necessary for the examiner to construe the claims. For terms that are not well-known in the art, or for terms that could have more than one meaning, it is necessary that the examiner select the definition that he/she intends to use when examining the application, based on his/her understanding of what applicant intends it to mean, and explicitly set forth the meaning of the term and the scope of the claim when writing an Office action. See *Genentech v. Wellcome Foundation*, 29 F.3d 1555, 1563-64, 31 USPQ2d 1161, 1167-68 (Fed. Cir. 1994)."

Applicants appreciate the detailed discussion provided in the office action discussing the factors related to undue experimentation. However, the Office Action fails to comply with the requirements set forth above in that no construction and analysis of the claims was set forth in the Office Action. The only discussion of the claims in the office action is on page 4, where it sets forth: "The claims are overly broad because the claims encompass any type of existing manifested and latent malady for diagnostics and treatment, which includes diseases which do

not have any medically recognized treatments." This broad statement fails to "explicitly set forth the meaning of the term and scope of the claim" as is required for a rejection for enablement.

Instead, the Office Action focuses not on the claims, but on the specification and the specification's teachings that a large number of maladies may be diagnosed and treated using embodiments of the invention. The Office Action repeatedly takes issue with the fact that the specification fails to associate specific resistance measurements with specific maladies. Regarding this issue, the specification clearly teaches that the claimed invention is different from existing EAV or EDS devices, in that it does not rely on the teachings of old systems of measuring the differing resistances of different meridian access points. Instead, the embodiments of the invention function differently in that one or more stable access points having balanced resistance readings (see specification at page 30 lines 2-19, for example (all references herein are to the specification as filed)), e.g. having readings between 45 and 55, which are terms and readings that are well known and defined in the art. (See, for example, the Barrett article cited with the Office Action at page 2, first full paragraph, which uses nearly identical language.)

Once one or more stable data access points is located, the claimed invention functions by applying stressing filters that cause the resistance reading at the stable data access point to move outside of the previously-measured stable range (e.g. outside of the 45-55 range). As is clearly taught in the specification, and contrary to the apparent interpretation of the Office Action, it is not the measured resistance value that corresponds to a malady, but the applied filter that causes the imbalance that corresponds to the malady. (See specification at page 38 lines 1-11, for example.) As such, the specification fully enables the invention as it not only teaches the

practice of the invention, but also clearly suggests to one of skill in the art how to obtain, through simple routine experimentation, knowledge of which filters correspond to which maladies.

Applicants therefore respectfully disagree regarding the finding that undue experimentation is required to make and use the claimed invention, and respectfully submit that any experimentation necessary is routine and well within the practice and abilities of one of skill in the art. A specific discussion showing that the claimed invention is enabled is set forth below.

Claim 1:

Claim 1 reads as follows:

1. A computerized meridian linking diagnostic and treatment system for diagnosing and treating energy disturbances manifested as latent maladies within a patient, said system comprising:

(a) a computer and computer system capable of storing information thereon and executing one or more computer software functions that control said system, said computer software functions comprising:

a meridian linking function that links all the meridians in a patient to form an interconnected meridian network;

a data access point stabilizing function that establishes and stabilizes one or more data access points as stable reference points having resistance measurements within a pre-determined stable range;

a filter testing function that utilizes customized filters to stress said meridian network to reveal manifested and latent maladies in said patient and to automatically load pre-determined products/remedies identified as effective against said maladies revealed by said customized filters;

an amplification function for varying the amplitude and intensity of said customized filters to reveal both manifested and latent maladies;

a remedy finding function that identifies and isolates a single, most effective product/remedy from said loaded products/remedies;

a prescription function that assigns prescription constraints to said single, most effective remedy; and

(b) a meridian linking diagnostic and treatment device controlled by the computer that outputs one or more filters to a patient through a meridian network, as directed by said computer software functions, using a single stable reference point.

Upon review of the Office Action, it appears that the primary objection to the claims is that the claimed invention can be used to diagnose and treat theoretically any manifested and/or latent disease, including diseases not having medically recognized treatments. However, Applicants believe that this objection is based upon a misinterpretation of the claims, and is further based on improper reading of limitations from the specification into the claims. Claim 1 does not recite a system for simultaneously diagnosing and treating all diseases, regardless of whether the system is actually or theoretically capable of being used for diagnosing and treating all diseases. Applicants will therefore analyze the scope of the claimed invention of claim 1, and will show that any experimentation needed to practice the invention is not "undue."

The preamble for claim 1 recites a system and a proposed purpose for that system. The features of the system are recited in sufficient detail to give life and meaning and understanding to the claim without importing any limitations from the preamble. As such, the preamble is not necessary to give life and meaning to the claim and may be ignored. (See M.P.E.P. § 2111.02: "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)," emphasis added.) Even if the preamble is interpreted as imposing limitations upon the claimed invention, the scope of the preamble is properly enabled with minimal (not "undue") experimentation.

By way of example (where the preamble is viewed as imposing limitations on the claimed invention – which Applicants dispute, as set forth above), the purpose of the claimed invention as recited in the preamble of claim 1 is met by a system for treating a single malady and by a system for treating only a few maladies, as long as the system incorporates the non-preamble limitations of claim 1. Determining the filters for diagnosing and/or treating one or several maladies is a matter of simple (i.e. not "undue") experimentation well within the common practice of one of skill in the art.

One method of determining the desired filter(s) that would be instantly apparent to one of skill in the art upon reading the specification is to locate a patient previously diagnosed with the malady for which a diagnosing filter and one or more treatment filters is desired. In the manner recited in the specification at page 7 lines 6-11, page 23 lines 10-13, and page 36 line 22-page 40 line 18, for example, a practitioner could easily test the previously-diagnosed patient with a large number of filters to determine which filter or filters causes an imbalanced reading. As set forth in the specification at page 40 lines 5-6, this may be done with all filters automatically to determine which filter(s) cause an imbalance in the linked meridian network. (See also the specification at page 41 line 15-page 42 line 7.)

In this way, one of skill in the art would be able to associate one or more filters with the patient's diagnosis. If further confirmation of the association is desired, additional pre-diagnosed patients might be similarly challenged and tested, and the certainty of the filter association improved. Such testing is well within the skill and routine of one in the art. This would not be considered complex for a single malady. To build a database of all such filters for all maladies

would certainly be time-consuming, but would also be routine. M.P.E.P § 2164.01 sets forth that "The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm"n 1983), *aff'd. sub nom.*, *Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404." This type of testing for the construction of databases of associated testing data is exactly the type typically and routinely engaged in by those in the biomedical arts. Thus, any experimentation required to achieve diagnosis of maladies is not "undue." This is especially true given the speed with which computerized systems may be used to perform such testing.

Similarly, the process recited in the specification at page 42 line 11-page 44 line 22 and especially page 44 lines 5-18 may be utilized to determine treating frequencies in a similar fashion. Again, such bulk testing may be aided by automated and/or computerized processes, and filters effective at restoring homeostasis may be stored and associated with the stressing filter for treatment purposes. Such testing is also well within simple routine experimentation by on of skill in the art, regardless of whether the person of skill in the art is already familiar with potentially-useful filters or not.

Therefore, for all the reasons set forth above, there is no enablement issue with the preamble of claim 1. As discussed above, this appears to be the primary enablement issue of concern in the Office Action. However, the remaining limitations of claim 1 will be discussed briefly below.

As computers and computer systems capable of storing information and executing computer software functions are well known, the second phrase of claim 1 is enabled. A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). The claimed software functions of the meridian linking function and the data access point stabilizing function are adequately described and enabled in the specification at page 27 line 19-page 36 line 21.

The claimed software function of a filter testing function is enabled, as set forth in detail above, in the specification at page 7 lines 6-11, page 23 lines 10-13, and page 36 line 22-page 40 line 18, for example. The claimed amplification function is enabled at page 48 line 4-page 51 line 4. The claimed remedy finding function is enabled at page 42 line 11-page 48 line 3. The claimed prescription function is enabled at page 51 line 5-page 52 line 1. Finally, the meridian linking diagnostic and treatment device is enabled at page 24 line 3-page 26 line 6, for example.

Regarding the factors for evaluating enablement delineated in the Office Action, Applicants respectfully submit that the factors recited have been misapplied in this case, as discussed in detail below.

The Breadth of the Claims

Regarding claim breadth, the Office Action sets forth that the claims encompass any type of existing manifested and latent malady, including diseases not having any medically-recognized treatments. Applicants respectfully agree that the claims are broad and read on systems and methods that utilize the specifically-recited filter functions, methods, etc. as recited

in the claims to treat any type of malady. However, Applicants respectfully note that the claims do not recite nor do they require the ability to simultaneously diagnose and treat all maladies. Instead, claim 1 recites a system "for diagnosing and treating existing manifested and latent maladies." As is axiomatic, this recitation of purpose is only given weight and meaning insofar as it is necessary to import life and meaning into the claims, and even to the extent that it is given weight in the claim, the claim at most would require a system that diagnoses and treats two or more maladies. As such, only simple routine experimentation of the type set forth above and enabled by the specification is required to achieve the claimed invention. Extending such simple experimentation to create a large database of malady-corresponding filters, even if necessary for claim 1 (which it is not), is simply a matter of repeating routine experimentation and is therefore also routine.

The Nature of the Invention, and the Level of One of Ordinary Skill

As set forth in the Office Action, those of skill in the art have a strong understanding of the inter-relationships between disciplines and would understand that certain amounts of experimentation may be required. As such, those of skill in the art would find it routine to perform the type of experimentation set forth above to achieve the ability to diagnose and treat desired maladies.

The Amount of Guidance, and the Existence of Working Examples

Applicants have addressed, above, the manner in which the specification clearly sets forth how the claimed invention may be practiced and the manner in which filters may be tested for their stressing/diagnosing and balancing/treating capabilities. As such, one of skill in the art

would find any necessary experimentation to be simply routine and not "undue." Furthermore, as clearly set forth in the specification, and as discussed above, there is no correlation of resistance levels with particular maladies recited in the claims or alleged in the specification. Therefore, the lack of such correlations in the specification is immaterial, as that is not how the claimed invention functions.

The State of the Prior Art and the Level of Predictability in the Art

The Office Action focuses entirely in this section on alleged unpredictability of correlations between skin resistance and diagnosed maladies. Therefore, this entire analysis is immaterial to whether the claimed invention is enabled, as the claimed invention does not rely on correlations between skin resistance and diagnosed maladies, but instead relies on correlations between filters that cause imbalanced skin resistance measurements that were previously balanced, and between filters that re-balance the skin resistance measurements.

Regarding Semizzi et al., Semizzi teaches that electrodermal instruments can have a reliable diagnostic value. Semizzi teaches that rigorous testing is necessary before claiming efficacy, which is a premise well-known in all the biomedical arts.

Regarding Pearson et al., Pearson concludes that caution is necessary when using electrodermal devices and interpreting their results. Primarily, Pearson was concerned with varying resistance measurements on and off meridian sites. As set forth in detail above, the claimed invention does not rely on interpretations of varying resistances at varying meridian sites, but relies on varying resistances caused by the application of various filters (stressing

and/or treating, etc.) at single sites. As such, Pearson is not particularly applicable to evaluating the predictability of the present invention.

Regarding Ko et al., Ko merely reports the results of a survey of patients to determine how many use complementary and alternative medicine (CAM) systems and their perception of the efficacy of such systems. Ko indicates that 18% of respondents report using CAM therapies, but does not distinguish between the various modalities in the report of efficacy. Therefore, Ko, at best, merely reports Ko's opinion that electrodermal testing is either unproven or disproven. Ko says nothing relating to the functionality of the present invention.

Regarding Barrett, Barrett is clearly antagonistic to electrodermal devices in general, and should therefore be given weight only insofar as it expresses Barrett's personal distrust of such devices. Barrett does not discuss any devices having a functionality or utilizing a method similar to the claimed invention, and is therefore not particularly helpful in evaluating the level of predictability of the presently-claimed invention.

The Quantity of Experimentation

Based on all the above, any experimentation necessary would clearly be routine and not "undue." Again, this portion of the Office Action focuses almost entirely on the experimentation necessary to correlate levels of resistance and particular diseases. This is not what is claimed by the claimed invention, and is therefore irrelevant to determining whether the claimed invention is enabled.

Therefore, for all the reasons set forth above, all limitations of claim 1 are fully enabled by the specification as filed. As set forth above, claim 1 does not require a diagnostic and treatment system that simultaneously diagnoses and treats all manifested and latent maladies. Indeed, a system that diagnoses and treats a single manifested or latent malady or one that diagnoses and treats a small number of manifested or latent maladies using the recited claim limitations would clearly infringe claim 1. As set forth above, determining the filters for such diagnosis and treatment is a matter of simple, routine experimentation well within the common practice and skill of one of ordinary skill in the art. As such, "undue" experimentation is not necessary to practice the invention claimed in claim 1.

Claims 2-9 and 23-26:

Claims 2-9 and 23-26 contain similar limitations to those discussed above with respect to claim 1 or are dependent upon similar claims. As such, Applicants submit that such claims are also described by the specification as filed in a manner sufficient to enable one of skill in the art to make, use, and/or practice the invention for all the reasons set forth above.

Again, Applicants respectfully note that the Office Action lacks a detailed and explicit construction of the claims for which a lack of enablement is alleged, as is required by M.P.E.P § 2164.04. Therefore, the rejection of all the claims for lack of enablement cannot stand. Applicants therefore respectfully request removal of the rejections of claims 1-9 and 23-26 for lack of enablement.

New claims 27-39 do not recite any diagnosis or treatment of maladies. As such, the new claims do not implicate any of the enablement issues addressed above or set forth in the Office Action. Applicants respectfully request favorable treatment of claims 27-39 accordingly.

CONCLUSION

Applicants submit that no new matter has been added and that the claims are now in condition for allowance. Accordingly, Applicants request favorable reconsideration. If the Examiner has any questions or concerns regarding this communication, the Examiner is invited to call the undersigned.

DATED this 2 day of January, 2008.

Respectfully submitted,

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